REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-14 are pending in this application. Claims 10-12 reintroduces the text from the "range within a range" text of original claims 2-4 respectively. New claims 13 and 14 refers to the tear strength described in paragraph [0062] in the publication of this application. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE 35 U.S.C. 112, 1st PARAGRAPH REJECTION HAS BEEN OVERCOME

The rejection of claims 7 and 8 for lack of written description is not well understood. The Office Action refers to the lack of examples for the concentration gradient teaching or use of a covering layer which is a water-insoluble polymer and is impermeable for the active ingredient, but this is an argument for lack of enablement not lack of written description and no *Wands-style* analysis was offered in the Office Action.

With respect to written description, there is no requirement for examples especially when the claim language not only was part of the originally filed claims, but was also found in the specification (see paragraph [0033] and [0035] of the publication).

Satisfaction of the written description requirement is far less burdensome than presented in the Office Action. "[U]nder these circumstances, we consider the original claim in itself adequate 'written description of the claimed invention. It was equally 'written description' whether located among the original claims or in the descriptive part of the specification." see *In re Gardner*, 178 USPQ 149, (CCPA 1973)). MPEP 2163, section I. A. states in part:

> There is a ***strong presumption that an adequate written description of the claimed invention is present when the application is filed.*** *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the ***PTO has the initial burden of presenting evidence***

> ***or reasons*** why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). - emphasis added by applicants.

While reliance on case law is permitted if the facts of the case law are sufficiently close to the issue at hand, this is not the case with the recitation of the *Rochester* decision. This application is distinguished from *Rochester* in that the present case is not identifying a compound, but describing what is the effect on a compound by use of the applicant's dosage form. Furthermore, the state of the art is such that one of ordinary skill in the art would be able to determine, if directed, whether a concentration gradient exists and whether a covering layer is a water-insoluble polymer or not and whether that covering layer would be impermeable for an active ingredient or not.

Therefore, the rejection presented provides no evidence of lack of written description, is incongruous for the level of description already presented and relies on case law which is not related to the issue at hand. For these reasons, the strong presumption that adequate written description has been made has not been overcome in the Office Action and the written description requirement should be withdrawn.

III. THE 35 U.S.C. 112, 2nd PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 1-9 were rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. The applicants request reconsideration of this rejection for the following reasons.

The amendments to 1-4, 6 and 9 are believed to address the corresponding rejections made to these claims. However, with regard to claims 7 and 8 the nature of these rejections is not well understood.

With respect to claim 7, the layer has a concentration gradient and for claim 8, the covering layer is impermeable for the active ingredient and/or nutrient. What would one of ordinary skill in the art find unascertainable about this element of the invention? *See MPEP 2173.02.*[1] If the rejection is based on the scope of what can constitute an active ingredient, it is

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[1] "The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, ***not whether more suitable language or modes of expression are available***. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. ***Examiners are encouraged to suggest claim language to applicants to improve clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.***

noted that MPEP 2173.04 states in part that "Breadth of a claim is not to be equated with indefiniteness" *See In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971)).

IV. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

Claims 1-9 were rejected as allegedly being obvious by Nara et al. (US 6,245,351 - "Nara") in view of Horstmann et al. (US 6,800,329 - "Horstmann"). The applicants request reconsideration of this rejection for the following reasons.

While the Office Action identified features of the applicants' invention and partially identified the differences between the claimed invention and the teachings of Nara, the applicants' claimed invention and the Nara and Horstmann references did not appear to be considered as a whole as is required when making a determination of obviousness. *See MPEP 2141.02.*

First, the difference between Nara and the claimed invention is not limited merely to the step of drying the mixture or that the dosage is in film form for surface/topical adminstration (which are substantial differences in and of themselves), but also includes the additional differences that:

(1) the hydrophilic polymers crosslinked with at least one polyacrylic acid derivative (and for the claims as amended, the hydrophilic polymers are crosslinked by the polyacrylic acid derivative *in situ*)[2]; and

(2) there is no mention of the simultaneous spraying of an aqueous solution of the hydrophilic polymers and aqueous solution of the polyacrylic acid derivative.

As Horstmann does not address these differences, the combination of Nara and Horstmann do not render the applicants' claims for this reason alone as all claim elements are not taught or suggested by the combination of Nara and Horstmann.

In addition, even if Horstmann had taught all the missing elements, when considering Nara as a whole, it is not even related to the type of dosage forms which is taught both by the applicants' claimed invention and by Horstmann (i.e. film forms). Nara refers to an alternative

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2 Moreover, there appeared to be a misunderstanding in the Office Action about the teaching within Nara about crosslinking. The liquid coating composition used by Nara comprises of a water-insoluble substance, swellable polymer and an ***already crosslinked polymer***, i.e. the swellable polymer is ***not crosslinked*** to the crosslinked polymer.

form of an ***enteric*** capsule consisting of a drug core with an outer coating which is clearly identified in the "Summary of the Invention" (see col. 1, lines 50-57 – "…to develop a controlled-release composition for ***oral administration*** coated with a coating composition which is capable of releasing drug at higher rates in the ***intestinal tract*** than in the stomach to maintain an almost constant plasma concentration of drug and ensure effect of drug in the body for an extended period of time.")

In contrast, Horstmann is directed to the production of sheet-like administration forms which is completely different than the controlled-release compositions of Nara. Not only would one of ordinary skill in the art look to Hortsmann to make modifications to the invention of Nara, given the differences in forms, there is no expectation of success that taking an isolated element from a sheet-like administration forms could be incorporated into the controlled-release composition of Nara while maintaining the intended use of Nara, i.e. releasing drug at higher rates in the ***intestinal tract*** than in the stomach to maintain an almost constant plasma concentration of drug.

Therefore, it would not have been obvious to combine Horstmann with Nara as there was no reason to combine teachings from disparate inventions nor was there a reasonable expectation of success for the combination proffered in the Office Action.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
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